



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/772,801	01/30/2001	Diane McGhee	20520/1 (S-8332-CIP)	1002

7590

03/23/2004

Mark S. Leonardo
Brown Rudnick Freed & Gesmer
Box IP, 18th Floor
One Financial Center
Boston, MA 02111

EXAMINER

GHALI, ISIS A D

ART UNIT	PAPER NUMBER
----------	--------------

1615

DATE MAILED: 03/23/2004.

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/772,801

Applicant(s)

MCGHEE ET AL.

Examiner

Isis Ghali

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 April 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/30/2002</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The finality of the last office action mailed 01/05/2002 is withdrawn, and a new action on the merit is issued.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-30 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-75 of U.S. Patent No. 6,180,132. Although the conflicting claims are not identical, they are not patentably distinct from each other because both of the present application and the issued patent claim a resilient hydrogel comprising polyurethane, polyalkyl diol, water, accelerator and bacteriostatic agent; and method of its production. The "comprising" claim language of

Art Unit: 1615

the issued patent permits the presence of other ingredients in the instantly presented claims.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 1, 12 and 23, the expression "accelerator" does not set out the metes and bounds of the claim. Recourse to the specification does not define the expression "accelerator". Clarification is requested.

Regarding claim 6, the expression "other antimicrobial and other additives" does not set out the metes and bounds of the claim. Recourse to the specification does not define the expression those other antimicrobial agents and other additives. Clarification is requested.

Regarding claims 9 and 10, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claims 29 and 30 recite the limitation "dressing" in the first line of each claim. There is insufficient antecedent basis for this limitation in claims 29 and 30 or in claim 23 from which the claims depend.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 12-14, 18-30 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,160,328 ('328).

US '328 disclosed a hydrogel composition for wound dressing comprising from 8-15% by weight of polyurethane prepolymer, 15-30% by weight polyhydric glycol selected from the group consisting of polypropylene glycol and polyethylene glycol, the balance water and the accelerator (col.4, lines 49-64). The hydrogel material can form circular layer having dimension of 3.0-7.5 cm and thickness from 600-1500 microns (col.6, lines 19-31). The reference disclosed method of making the gel comprising the steps of mixing the components, curing, and molding the hydrogel (col.5, line44-col.6, line5). The hydrogel composition disclosed by the prior art that have the same ingredients in the same amounts as the instant claims inherently will have the same physical properties such as resiliency and the intended use as self-supporting of the instantly presented composition.

In the response filed 4/10/03, applicant traversed the above rejection by arguing that the prior art hydrogel is not self-supporting evident by the prior art using the support layer.

Art Unit: 1615

In response to the above argument, the examiner position is that the recitation of the such intended use in the claim permeable does not limit the scope of the claim since such statement merely define the context in which the invention operates, and the body of the claim defined the subject matter of the claimed invention. The claims are directed to composition, and all the elements of the composition are recited in the body of the claim, and the permeable is not essential to understand limitations or terms in the claim body. and does not provide antecedent basis for terms in the body of the claim.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Art Unit: 1615

10. Claims 2-11, 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 328 in view of US 4,846,165 ('165) or US 5,219,335 (335).

The teachings of US '328 are discussed under 102 rejection above. However, US '328 does not teach the specific antimicrobial agents as claimed by applicants.

US '165 teaches a wound dressing membrane comprising gel comprising polyurethane, polyethylene glycol, filler, and therapeutic agents (abstract; col.5, line 5; col.7, line 6; col.8, line 48; col.9, line 22). The therapeutic agents include chlorhexidine, tetracyclines, and antifungal agents such as micronazole and nystatin (col.9, lines 45-68). The therapeutic agents are useful in treating mammals and fighting infection (col.9, lines 15-25).

US '335 teaches hydrogel wound dressing composition that comprises ingredients to absorb fluids and promote healing of the wound including antibacterial agents including metal ions, silver sulfadiazine, and bacitracin; dyes; pigments; and flavoring (col.2, lines 37-59).

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a composition useful for wound dressing comprising polyurethane and glycol as disclosed by US '328, and add antimicrobial agents to the composition as disclosed by any of US 165 or US '335, motivated by the teaching of any of the references that antimicrobial agents promote wound healing, and motivated by the art recognized purpose of using the antimicrobial agents in wound dressing, with reasonable expectation of having wound dressing comprising polyurethane, glycol and antimicrobial agent that treat wounds without infection with great success.

11. Claims 1-11, and 23-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,932,200 ('200) in view of any of US '165 or US '335.

US '200 teaches resilient hydrogel used for wound dressing, surgical implants, and pressure absorbing applications (abstract; col.2, lines 25-32; col.3, lines 1-5). The gel comprises polyurethane, alkyl diol selected from ethylene glycol and propylene glycol, water, colors, and fragrance (abstract; col.2, lines 38-40, 49-51; col.3, lines 24, 32-38). The gel includes antibiotics and oils (col.10, lines 36-42).

US '200 does not teach the specific antimicrobial agents as claimed by applicants, or the amount of different ingredients in the composition.

The amounts of different ingredients do not impart patentability to the composition claims, absent evidence to the contrary.

The teachings of US '328 and US '335 are discussed above.

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a composition useful for wound dressing comprising polyurethane and glycol as disclosed by US '200, and add antimicrobial agents to the composition as disclosed by any of US 165 or US '335, motivated by the teaching of any of the references that antimicrobial agents promote wound healing, and motivated by the art recognized purpose of using the antimicrobial agents in wound dressing, with reasonable expectation of having wound dressing comprising polyurethane, glycol and antimicrobial agent that treat wounds without infection with great success.

Art Unit: 1615

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615

IG

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

